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Preparation and Evaluation of Floating Tablet of Pantoprazole Sodium On Peptic Ulcer

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ABSTRACT
Floating drug delivery system (FDDS) helps to improve the buoyancy property of the drug over the gastric fluids and hence maintain the longer duration of action. It is helpful in minimizing the dosing frequency. The main aim of this study was to formulate and evaluate the performances of floating pantoprazole. FTIR studies confirmed compatibility between drugs and polymers. the drug content was found to be between 97.11 to 99.56,floating lag time was less than 1 min, and floating duration was more than 12hrs. In vitro drug release showed results in the range of 82.27to 97.6, at 12 hrs for all the formulations. Thus, floating pantoprazole reduce dosing frequency and enhance the residence time of the drug in the stomach.

Keywords - Pantoprazole, Floating drug delivery system, Sustained release, controlled release, Floating tablet, Evaluation.

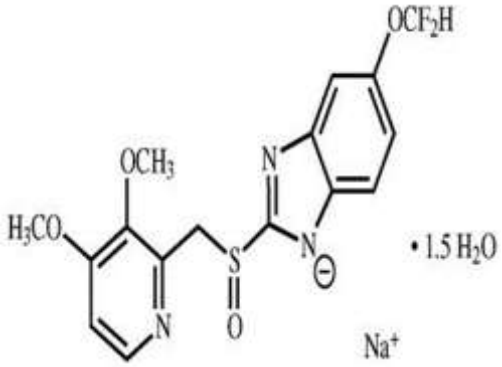
I. INTRODUCTION

Floating drug delivery systems have a bulk density less than gastric fluids and so remain buoyant in the stomach without affecting the gastric emptying rate for a prolonged period. While the system is floating on the gastric contents, the drug is released slowly at the desired rate from the system. After release of drug, the residual system is emptied from the stomach. This results in an increased gastric retention time and control of the fluctuation in plasma drug concentration. Pantoprazole is protein pump inhibitor (PPI) used for the treatment of acute duodenal ulcer, acute benign gastric ulcer, gastroesophageal reflux disease (GERD) and prophylactic use in duodenal ulcer. It acts by competitive inhibition of H+ /K+ ATPase enzyme of the gastric parietal cells resulting in reduced gastric acid secretion i.e., having local action in the stomach. The recommended oral dosage is generally 45 mg for acute duodenal ulcer, acute benign gastric ulcer, and gastro esophageal reflux (GERD) and is prescribed for the duration of 8-12 weeks. The drug has a short biological half-life (1-2 hrs) and local action in stomach which makes it suitable candidate for FDDS.As a result, drugs especially those are having absorption windows in the stomach face serious bioavailability issues due to short residence time (Bisht et al., 2013; Gaikwad et al., 2012). It is evident from the reported literature that growing interest has been observed in the development of oral Controlled release dosage forms that capable to deliver the drug at a predetermined rate for a prolonged period. Floating drug delivery systems (FDDS) is one, amongst the several approaches that are likely used in prolongation of the gastric residence times (GRT) (Balata, 2014).

DRUG PROFILE

PANTOPRAZOLE SODIUM

Pantoprazole Sodium is a proton pump inhibitor drug used for treatment of erosion and ulceration of the esophagus caused by gastro esophageal reflux disease.



(Chemical Structure of Pantoprazole Sodium)
Name of Drug: Pantoprazole sodium
Tradename: Protonix
Structural Formula: C16H14F2N3NaO4S
Molecular Weight: 405.351636 g/mol
IUPAC Name: sodium;5-(difluoromethoxy)-2-[(3,4-dimethoxypyridin-2-yl)methylsulfinyl]benzimidazol-1-ide.
Dose: 40mg

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Bioavailability - absolute bioavailability about 77%. Peak plasma concentrations attained about 2.5 hours after single or multiple 40-mg oral doses AUC after single oral 40-mg dose about 39% higher in children 6–11 years of age and about 10% higher in adolescents 12–16 years of age compared with adults.
Onset - 51% mean inhibition of gastric acid secretion within 2.5 hours after a single 40-mg oral dose; 85% after daily administration for 7 days. 15–30 minutes after single 20- to 120-mg IV infusion. About 96% suppression of pentagastrin-stimulated acid output within 2 hours after 80-mg IV infusion.
Duration - 24 hours after single IV infusion. Median percentage of time gastric pH ≥4 similar after 40 mg IV or orally daily for 5 days.
Distribution - Plasma Protein Binding - 98%, principally albumin.
Elimination – Metabolism - Metabolized in the liver, principally by CYP2C19, and to a lesser extent by CYP3A4. Metabolites appear to be inactive.
Elimination Route - Excreted in urine (about 71%) and feces (18%); no unchanged drug excreted in urine.
Biological Half Life: 1-2 hours
Ionization constent : Pka_1 of 3.92 and Pka_2 8.19
Solubility: Pantoprazole sodium is freely soluble in water, very slightly soluble in phosphate buffer at pH 7.4
Appearance: white to off-white crystalline powder.

Machanism of action: The mechanism of action of pantoprazole is to inhibit the final step in gastric acidproduction. In the gastric parietal cell of the stomach, pantoprazole covalently bindsto the H+/K+ ATP pump to inhibit gastric acid and basal acid secretion. The covalent
binding prevents acid secretion for up to 24 hours and longer.
Uses: Gastroesophageal reflux (gerd)

- Pathologic gi hypersecretory conditions
- Duodenal ulcer
- Gastric ulcer
- Crohn's disease-associated ulcers

Side Effects – Diarrhea**,** Flatulence**,** Headache**,** Nausea**,** Stomach pain**,** Vomiting**,** Dizziness.
Contraindications- Known hypersensitivity to pantoprazole, any ingredient in the formulation, or to other substituted benzimidazoles (e.g., esomeprazole, lansoprazole, omeprazole, rabeprazole).
Precautions - Sensitivity Reactions**,** Anaphylaxis - Anaphylaxis reported with IV pantoprazole. Immediately discontinue drug and institute appropriate medical intervention, Gastric Malignancy - Response to pantoprazole does not preclude presence of occult gastric neoplasm, Atrophic Gastritis, Clostridium difficile Infection, Bone Fracture, Hypomagnesemia, Cyanocobalamin Malabsorption.

CHARACTERIZATION OF FLOATING TABLET PANTOPRAZOLE SODIUM

PREFORMULATION STUDIES - Most of the floating formulation is either a single unit type or multi-unit type of preparation. The quality of tablet, once formulated by rule, is generally dictated by the quality of physicochemical properties of blends. There are many formulations and process variables involved in mixing and all these can affect the characteristics of blends produced. The various characteristics of blends tested as per Pharmacopoeia.

1. **Compatibility studies between drugs and excipients**: The physical compatibility study of drug and excipients are carried out to determine the possible physiochemical interactions. The study can be performed using FTIR, DSC or X-Ray diffraction technique (Haranath et al., 2017).
2. **Angle of Repose**: In this study accurately weighed mixture of powder/granules/microparticles are placed in a funnel. The funnel may be adjusted in such a way that the tip of the funnel just touches the apex of the heap of blends. The blends are allowed to flow through the funnel freely on a horizontal surface. The diameter of the speeded mass (powder/granules/ microparticles) will be measure, and the angle of repose can be determined by using the following equation (Saritha et al., 2012).

$\tan \theta = h/r$

Where, θ = angle of repose, h = height in cm, r =radius in cm.

3. **Bulk density** Apparent bulk density was measured by pouring the preweighted blend of powder into a graduated cylinder. Density is defined as weight per unit volume. Bulk density is defined as the mass of the powder divided by the bulk volume and is expressed as gm/cm3. The bulk density of a powder is

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determined largely by particle size distribution, particle shape, and particle adhesion. Bulk density has a big impact on the size of containers needed for raw material and mix handling, shipping, and storage. It's also crucial in size mixing machines. Without compacting, a 2 gramme powder blend was sieved and poured into a dry 20 ml cylinder. The powder was carefully levelled without compacting, and the apparent volume, Vo, was determined. The bulk volume of the blend was determined, and then the bulk density may be calculated by using the formula.

Bulk Density = M / Vo

Where, M = mass of the powder

Vo = apparent volume of powder

Angle of Repose (θ)	Nature of Flow
<25	Excellent
25-30	Good
30-40	Passable
>40	Very poor

4. **Tapped density** The measuring cylinder containing a known mass of blend is tapped for a fixed duration of time and from a specific height as per standard protocol. The initial volume occupied in the cylinder is measured and the same processes are applied after tapping. The tapped density may be calculated by using the following formula

Tap = M / V

M = mass of the powder

V = volume of the powder after tapping

5. **Carr's index (I):**The compressibility index can be determined from the value of bulk and tapped densities (Sood et al., 2012).

The percentage compressibility of the bulk drug can be determined using the following formula. It is expressed in percentage –

Carr's Index (I) = Dt-Db/Dt×100

Where Dt is the tapped density of the powder and Db is the bulk density of the powder.

Carr's index value (as per USP)

Carr's index	Properties
5 – 15	Excellent
12 – 16	Good
18 – 21	Fair to Passable
2 – 35	Poor
33 – 38	Very Poor
>40	Very-very poor

6. **Hausner ratio**: Hausner ratio can be calculated by the formula:

Hausner ratio = Tapped Density/ Bulk Density

POST-COMPRESSION PARAMETERS: The single unit floating dosage form(tablet) can be subjected toquality control tests like weight variation, hardness, thickness, friability, and content uniformity.

1. **General appearance** - The general appearance of tablets, visual identity and overall 'elegance' is essential for consumer acceptance, control of lot-to-lot uniformity and general tablet uniformity and for monitoring the production process. The control of general appearance involves measurement of attributes such as a tablet's size, shape, color, presence or absence of odour, taste, surface textures, physical flaws and consistency.
2. **Size and Shape** - The type of tooling determines the shape and the dimensions of compressed tablets during the compression process. Tablet thickness varies with changes in die fill, particle size distribution, and packing of the powder mix being compressed, as well as tablet weight, at a constant compressive pressure, while thickness varies with variation in compressive load at a constant die fill. Only if the tablet granulation or powder mix is suitably uniform in particle size and particle size distribution, if the punch tooling is of

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consistent length, and if the tablet press is clean and in excellent operating order will tablet thickness be consistent from batch to batch or within a batch.

3. **Determination of drug content in tablets** Randomly3 tablets from each batch are selected and transfer to a 100 ml volumetric flask contain suitable medium. Store the content for 48 hours then took 1ml from each of the volumetric flasks and transfer to the test tube. The collected samples are analyzed after suitable dilution using a UV spectrophotometer at a suitable wavelength. The linearity equation obtained from the calibration curve is used for the estimation of drug content (Doddayya, 2013; Mondal et al., 2017).
4. **Determination of hardness:** The hardness of the tablet is determined by using Monsanto or Pfizer Hardness tester. The tablets are placed between two loads, adjusted with a spindle, and the pressure required to break the tablets are measure. The average value of 3 tablets may be noted.
5. **Determination of thickness of tablets**- The thickness of tablets can be determined using slide calipers. The average thickness of five individual tablets may be reported as the thickness of the prepared tablet.
6. **Determination of friability** Roche friabilator may be used to perform the study. Previously weighted 20 matrix tablets may be placed in the friabilator and rotation speed and duration of rotation may be set as per the standard protocol. After completion of the rotation, tablets are taken out from the machine and reweighted, the difference is noted as per the following formula

F = 100 (1-w0 /w)

7. **Determination of weight variation** - Around 20 tablets were selected at random and weight accurately. Now, the average weight of the tablets may be calculated. Then the deviation of individual weight from the total weight will be calculated. The obtained result will be compared with the given standard limits as per IP.
8. **Disintegration Time:** In-Vitro disintegration time can be determined by using the disintegration test apparatus. For this, the tablet is placed in each of the six tubes of the apparatus and one disc is added to each tube. The time taken for the complete disintegration of the tablet is measured.
9. **Differential scanning calorimetry (DSC) -** The possibility of drug-excipient interaction was further investigated by differential scanning calorimetry. DSC curve for each pure powder of amlodipine, hydroxypropyl methylcellulose (HPMC) K15M, K100M, in addition to the physical mixture of the optimum formula of amlodipine in the presence of polymers (Precompression) and compressed tablet (post-compression) analysis, was implemented using DSC instrument. The samples were accurately weighed and heated in a sealed aluminum pan at a rate of 10 °C/min. within a 10 and 250 °C temperature range under a nitrogen flow of 40 ml/min (Pawar & Dhavale, 2014).
10. **Buoyancy studies**: In this study, the onset time of floating and duration of floating are measured. Randomly selected tablets are placed in a 250 ml beaker, containing 200 ml of 0.1 N HCl. The time required for the tablet to rise at the surface and the entire duration of time of tablet remain floated is determined (Reddy, 2018).
11. **In Vitro Dissolution Studies**: The in vitro dissolution study may be performed by using a United States Pharmacopeia (USP) type II (paddle) apparatus at a rotational speed of 100 rpm. The dissolution test is performed using 900 ml of 0.1N HCl at 37oC ± 0.5oC. A sample (10 ml) of the solution is withdrawn from the dissolution apparatus at predetermined time intervals for 24 hrs and the samples were replaced with pre-warmed fresh dissolution media. The samples are filtered through a Whatman filter paper and diluted to a suitable concentration with 0.1 N HCl as a blank. The absorbance of the solution is measured at 276 nm using a UV spectrophotometer (Gaikwad et al., 2012; Taghizadeh Davoudi et al., 2013).

In-vitro drug release study: The in-vitro drug release may be carried out by using the dissolution test apparatus. Either a single tablet or floating microspheres are placed inside a dissolution apparatus. The study shall be carried out under a set of standard conditions. Throughout the study, the sink condition needs to be maintained and around 5 ml sample required to be transferred after a fixed time interval. The collected samples are analyzed under a UV spectrophotometer after suitable dilution. The amount of drug release may be

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calculated based on the obtained data (Rahim et al., 2015).

II. MATERIAL AND METHOD

MATERIAL – Pantoprazole sodium, Microcrystalline cellulose, Talc, Citric acid, Sodium bicarbonate, Carbapol, hpmc, pvp, Magnesium stearate,

DIRECT COMPRESSION TECHNIQUE

Floating tablets containing Amlodipine were prepared by direct compression technique using varying concentrations of different grades of polymers with Sodium bicarbonate and citric acid. All the components were precisely weighed and sieved using different mesh sizes. Then, except for Magnesium stearate, all other materials were evenly combined in a glass mortar. Magnesium stearate and purified talc (1 percent w/w) were added after adequate mixing of the medication and other components, and the mixture was stirred for another 2-3 minutes before being crushed using a single punch tablet machine. For all formulations, the tablet weights were kept constant.

COMPOSITION OF ALL THE FORMULATIONS (F1 –F6)

INGREDIENTS	BATCH F1	BATCH F2	BATCH F3	BATCH F4	BATCH F5	BATCH F6
Pantoprazole sodium	40	40	40	40	40	40
Microcrystalline cellulose	91.71	91.56	89.96	93.82	93.23	92.64
Talc	3	3	3	3	3	3
Citric acid	21.87	21.87	21.87	21.87	21.87	21.87
Sodium bicarbonate	44.5	43.2	45.2	44.6	42.9	45.5
Carbapol	15.62	16.35	17.62	16	16.95	15.55
Pvp	9.57	9.57	9.57	9.57	9.57	9.57
Hpmc	17.62	18.62	17.5	15.2	16.35	16
Magnesium stearate	6.15	6.15	6.15	6.15	6.15	6.15
TOTAL WEIGHT	**250**	**250**	**250**	**250**	**250**	**250**

*All the quantities are in mg

III. RESULTS AND DISCUSSION

PRE-COMPRESSION PARAMETERS - Pre-compression parameters play a vital role in improving the flow properties of pharmaceuticals, particularly in tablet formulation. These contain an angle of repose, bulk density, tapped density, Carr's index, and Hausner ratio.

1. **Angle of repose** - Values for the angle of repose were showed in table and found to be in the range of F1-24.41, F2-28.15, F3-32.35, F4-29.10, F5-30.56, F6-27.46 indicating good flow properties.
2. **Bulk density -** Values for the bulk density were showed in table are found to be in the range of F1-0.456, F2-0.489, F3-0.432, F4-0.467, F5-0.491, F6-0.486.
3. **Tapped density-** Values for the Tapped density were showed intable are found to be in the range of F1-0.603, F2-0.543, F3-0.598, F4-0.689, F5-0.982, F6-0.623.
4. **Carr's compressibility index** - Carr's Index is considered as a mensuration of powder bridge strength and stability. Thus, the values of compressibility index range between F1-16.29. F2-17.35, F3-19.18, F4-25.26, F5-22.45, F6-18.35 showed in table and this point outs good flowability of the powder blend.
5. **Hausner's ratio** - Hausner's ratio was measured to determine the inter-particulate friction and consolidation. The powder blend of most formulas has Hausner's ratio F1-1.23, F2- 1.04, F3-1.15, F4-.28, F5-1.09, F6-0.11 showed in table and thus indicate good flow properties.

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Pre-compression parameters

Formulations	Angle of repose	Bulk density (gm/cm2)	Tapped density (gm/cm2)	Compressibility index	Hausner's ratio
F1	24.41	0.456	0.603	16.29	1.23
F2	28.15	0.489	0.543	17.35	1.04
F3	32.35	0.432	0.598	19.18	1.15
F4	29.10	0.467	0.689	25.26	0.28
F5	30.56	0.491	0.982	22.45	1.09
F6	27.46	0.486	0.623	18.35	0.11

POST-COMPRESSION PARAMETERS

1. General appearance

DESCRIPTION AMLODIPINE	RESULTS
Colour	White crystalline powder
Odour	Odourless
Taste	Tasteless

2. Size and Shape

RAW MATERIAL (API)	NATURE OF SAMPLE
pantoprazole sodium	Fine powder

3. **Drug Content uniformity**- Values for the Drug Content uniformity was showed in table are found to be in the range of F1-97.11, F2-98.23, F3-99.25, F4-96.78, F5-97.45, F6- 99.56.
4. **Hardness test** - In table the hardness of the tablets was between (4.23-5.66) kg/cm2 and this confirms best characteristics of handling for all the batches.
5. **Tablet thickness** - The thickness of the tablets was shown in table which was between (4.1±0.04 - 4.5±0.03) mm. From these results, it can be detected that those batches with a low concentration of polymer showed less thickness of the tablets obtained due to lower concentrations of polymer. Moreover, a higher concentration of polymers produces more thickness for less dense tablets.
6. **Friability test** - The friability of the tablets normally performed and quite expectedly as showed in table. The results of all formulas were in the range (0.75±0.04-0.98±0.02)
7. **Weight variation** - Weight is compendial standard to assess the quality of tablets, and thus the weight variation test must indicate

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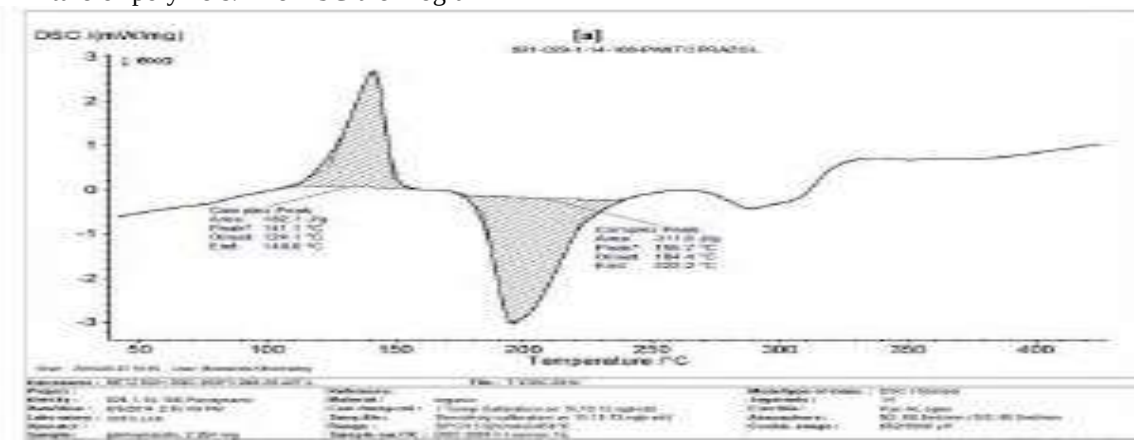
that all the tablets were uniform with low standard deviation values. The amlodipine floating tablets table indicates that weight variation of all formulas was in the range of F1-252±5, F2-251±5, F3-253±5, F4-255±5, F5-251±5, F6-253±5%.

8. **Disintegration times -** Disintegration test was conducted for all the formulation. The disintegration times of amlodipine containing HPMC K15M, HPMCK100M as super disintegrant. The increasing order of effectiveness of super disintegrants with respective to the disintegration time in amlodipine was found to be F1-11.56, F2-10.26, F3- 8.10, F4-9.45, F5-7.55, F6-8.09 min.

Drug content uniformity, Buoyancy Lag Time, tablet thickness, Total Floating Time, Hardness, Friability, Weight variation of tablets of different formulation F1 to F6.

Formulation	Drug-content uniformity (%)	Thickness	Hardness (Kg/cm2)	Friability (%)	Weight Variation (mg)	Disintegration times (min)
F1	97.11	4.3±0.01	5.46	0.61%	252±5%	11.56
F2	98.23	4.1±0.04	5.23	0.92%	251±5%	10.26
F3	99.25	4.4±0.01	4.89	0.84%	253±5%	8.10
F4	96.78	4.2±0.02	5.66	0.92%	255±5%	9.45
F5	97.45	4.5±0.03	5.49	0.75%	251±5%	7.55
F6	99.56	4.2±0.01	4.23	0.98%	253±5%	8.09

9. **Differential scanning calorimetry (DSC) -** The physical mixture showed no shift in the melting endotherm for pantoprazole sodium but giving broad endotherm indicating that there is no chemical interaction between the mixture of polymers. The DSC thermogram of the optimized formula depicted a similar melting point as observed with the pure pantoprazole powder. DSC thermogram of optimized formulation also shows some step changes in heat curve.



10. **Buoyancy / Floating Test -** The time between introduction of dosage form and its buoyancy on the simulated gastric fluid and the time during which the dosage form remain buoyant were measured. The time taken for dosage form to emerge on surface of medium called Floating Lag Time (FLT) or Buoyancy Lag Time (BLT) and total duration of time by which dosage form remain buoyant is called Total Floating Time (TFT).

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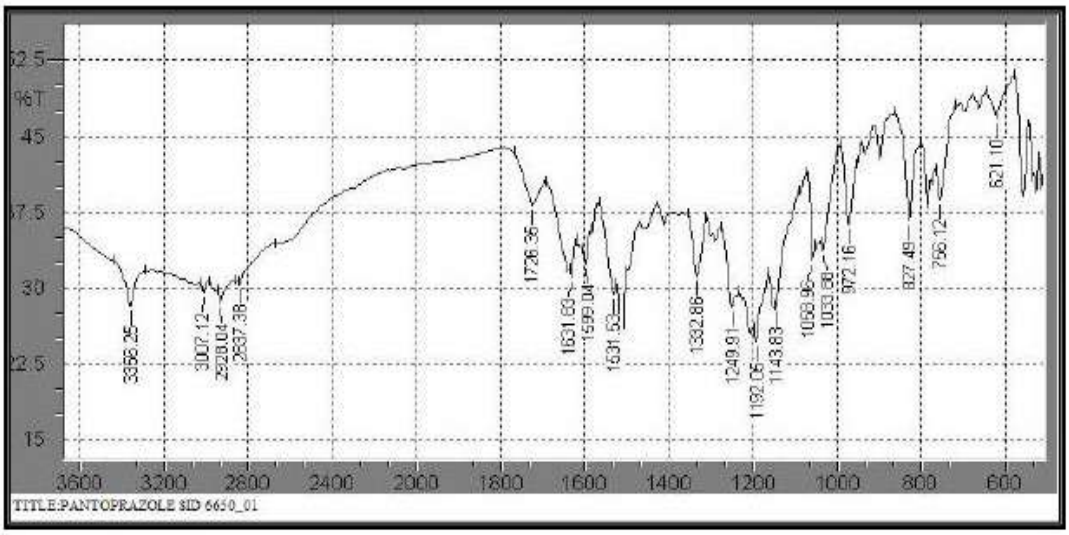
Buoyancy / Floating Test table

Formulation	Buoyancy lag time (sec)	Total floating time (hrs)
F1	4	14
F2	5	12
F3	4.5	10
F4	3.5	11
F5	4	13
F6	5	10

11. FTIR -

There was no disappearance of any characteristics peak in the FTIR spectrum of drug and the polymers used. This shows that there is no chemical interaction between the drug and the polymers used. The presence of peaks at the expected range confirms that the materials taken for the study are genuine and there were no possible interactions.

FTIR OF PANTOPRAZOLE:



12. In vitro dissolution studies – in vitro drug release studies

Dissolution parameters -

It was evident that formulations (F_1-F_6) showed rapid release within 14 h, Formulations (F_1 and F_6) were chosen to determine the effect of sodium bicarbonate ($NaHCO_3$) concentration on drug release. As shown in Table 11, raising **in vitro drug release studies dissolution parameter** the concentration of sodium bicarbonate had no statistically significant effect ($p>0.05$) on the drug release rate. As a result, water permeability is reduced. In terms of medication release rate, it was determined by the viscosity grade and concentration of the polymers used (El Nabarawi et al., 2017).

TIME (HRS)	CUMULATIVE % DRUG RELEASE					
	F_1	F_2	F_3	F_4	F_5	F_6
1.0	11.25	14.6	22.4	12.4	22.3	19.8

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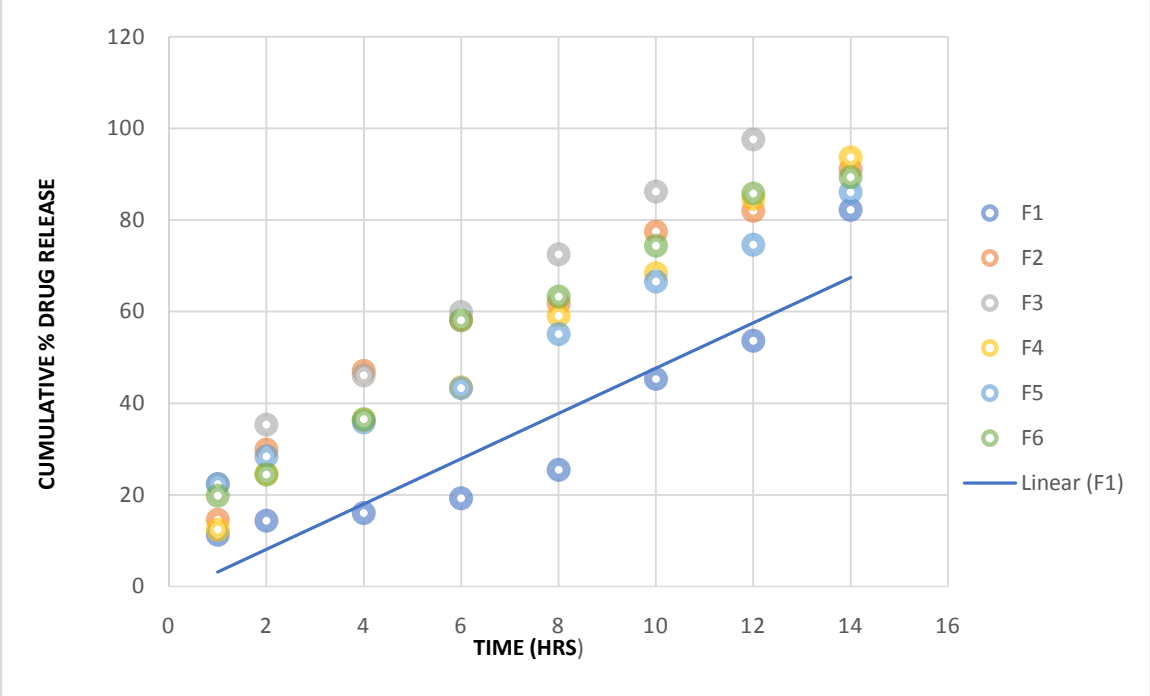
2.0	14.34	29.9	35.3	24.6	28.4	24.4
4.0	16.00	47.1	46.1	36.3	35.8	36.5
6.0	19.25	58.3	59.9	43.5	43.3	58.1
8.0	25.46	61.8	72.5	59.1	55.1	63.3
10.0	45.29	77.5	86.2	68.4	66.6	74.4
12.0	53.68	82.0	97.6	84.6	74.6	85.8
14.0	82.27	91.1		93.7	86.1	89.4



IV. SUMMARY AND CONCLUSION

In the present study the floating tablets of pantoprazole were prepared by direct compression method. The formulated pantoprazole shown better encapsulation efficiency and tablet shown satisfactory floating lag time and floating time. Series of experiments were performed during pre-formulation studies to select suitable excipient. Combination of different excipient were used to formulate pantoprazole floating tablets. Various Percentage of the excipient was also used to get best formulations with high bioavailability. Evaluation experiments such as friability, hardness, contentuniformity, thickness, weight variation, disintegration time were carried out and found that the results were satisfactory. Dissolution method was developed and validated. Dissolution of six batches of pantoparazole tablet were carried out and found that good reproducibility from batch to batch.

In accordance with present study, it was concluded that, floating tablet of pantoprazole sodium increase the gastric residence time as well as bioavailability and thereby shows increased therapeutic efficacy. The addition of gel forming polymer and gas generating agent sodium bicarbonate and citric acid was essential to achieve In vitro buoyancy. Method of preparation is simple, cost effective.

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